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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,345	12/01/2003	Johanna G. H. Ruseler-van Embden	2183-6192US	5255

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,345	RUSELER-VAN EMBDEN ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *20-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/01/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group I (claims 1-19) in the reply filed on 2/07/2006 is acknowledged.

Claims 20-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 2/07/2006.

Claims 1-19 are under examination in the instant office action.

Information Disclosure Statement

The information disclosure statement filed 12/01/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Please, provide copies of foreign patent documents and non-patent literature publications for examiner consideration and scanning into the instant IFW application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 and 5-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,906,457 (Ryan).

Claims are directed to a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Some claims are further drawn to the use of the inhibitor in amounts 1-20 % (wt/wt). Some claims are further drawn to the vehicle being in form of lotion, gel or aqueous solution, etc. Some claims are further drawn to the use of additional materials including adjuvant and some generic emollients, thickeners, preservatives and water. Some claims are further drawn to the composition being incorporated into various articles including wipe, cloth or dispenser.

US 4,906,457 (Ryan) discloses a skin care or topical pharmaceutical composition comprising an inhibitor of proteolytic activity that is derived from potato and a cosmetically or pharmaceutically acceptable vehicle (col. 3, lines 58-65). In particular, the composition comprises potato derived protease inhibitor in amounts about 0.01%, glycerol and water (example 1). The cited patent teaches the use of protease inhibitor in amounts approximately 10 mg/ml or higher in the topical composition (col. 2, line 24) or the use of protease inhibitor in desired proportions (col. 3, line 33). The composition is in a form of lotion, gel or aqueous solution, etc (example 1 or col. 2, lines 35-40) and contains additional generic materials suitable as generic emollients, thickeners, and preservatives within generic meaning of "emollients", "thickeners" and "preservatives" of the claims 9-11. The composition with protease inhibitor is applied to the skin, it is incorporated into various articles of manufacture including brush, wipe, etc. (col. 3 , line 55) and the aqueous composition with protease inhibitor is provided in

containers or dispenser within the broadest meaning of the claims 7, 8, 13-19. The particular composition of example 3 contains more than 50% of water within the broadest meaning of "Lanette cream" of the claim 12.

Thus, the composition of US 4,906,457 (Ryan) is identical to the claimed composition and, therefore, US 4,906,457 (Ryan) anticipates the claimed invention.

2. Claims 1-3 and 5-19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,950,509 (Geks et al).

Claims as above.

US 3,950,509 (Geks et al) discloses a skin care or topical composition comprising a cosmetically or pharmaceutically acceptable vehicle and a proteolytic activity inhibitor derived from potato (examples 3-4 at col. 3, line 32 and line 40; col. 4, line 1 and line 19) including kallikren-trypsin inhibitor derived from potatoes (col. 2, line 5 and example 1). The inhibitor is present in amounts from 1.5 wt. % (col. 2, line 54; col. 3, line 3) to about 3 wt. The composition is in a form of lotion, gel or aqueous solution, etc (col. 2, lines 25-27; examples 1 and 2) and contains additional generic materials suitable as generic emollients, thickeners, preservatives (see examples 1-4) within generic meaning of "emollients", "thickeners" and "preservatives" of the claims 9-11. The composition with protease inhibitor is applied to the skin, it is incorporated into various articles of manufacture including cloth (col. 3 , line 5) and the aqueous composition with protease inhibitor is provided in containers or dispenser within the broadest meaning of the claims 7, 8, 13-19. The composition of example 2 contains more than 50% of water within the broadest meaning of "Lanette cream" of the claim 12.

Thus, the composition of US 3,950,509 (Geks et al) is identical to the claimed composition and, therefore, US 3,950,509 (Geks et al) anticipates the claimed invention.

3. Claims 1, 2, 4, 5, 6, 8, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodis et al ("Naturally occurring protein crystals in the potato". Plant Physiol. 1984, 74:907-911).

Claims are directed to a composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Some claims are further drawn to the composition pH of 4.8-5.5. Some claims are further drawn to the vehicle being in form of aqueous solution or solution that can be absorbed into wipe, sheet, etc . Some claims are further drawn to the composition with 50% water and more.

The cited reference by Rodis et al discloses a composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle such as sodium acetate buffer, for example: see page 909, col. 2, last par., lines 1-2. The particular composition has pH of about 4-5. The cited reference also teaches that potato-derived proteins such as inhibitors of proteolytic activity are readily dissolved at pH 4-5. The aqueous solution(s) can be absorbed into wipe, sheet, etc and they contain 50% water and more within the broadest meaning of the claims 2, 5, 6, 8, 12 and 13.

Thus, the composition of the cited reference by Rodis et al is identical to the claimed composition and, therefore, the cited reference by Rodis et al anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) taken with Rodis et al ("Naturally occurring protein crystals in the potato". Plant Physiol. 1984, 74:907-911).

Claims are directed to a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Some claims are further drawn to the use of the inhibitor in amounts 1-20 % (wt/wt). Some claims are further drawn to the composition pH of 4.8-5.5. Some claims are further drawn to the vehicle being in form of lotion, gel or aqueous solution, etc. Some claims are further drawn to the use of additional materials including adjuvant and some generic emollients, thickeners, preservatives and water. Some claims are further drawn to the composition being incorporated into various articles including wipe, cloth or dispenser.

US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) are relied upon as explained above for the disclosure of a skin care or topical pharmaceutical composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Some of the cited compositions comprise potato protease inhibitor in amounts within the presently ranges. The cited references also teach and suggest that the amounts of active ingredients and genetic carriers can be adjusted as desired to provide for compositions in various forms.

The cited patents are silent about pH of the compositions with potato protease inhibitors. However, the reference by Rodis et al teaches that potato protease inhibitors are readily dissolved at pH 4-5 unlike neutral or alkaline pH.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use acidic pH in topical compositions of US 4,906,457 (Ryan) and US 3,950,509 (Geks et al) with a reasonable expectation of success in dissolving active ingredients such as potato-derived protease inhibitors. One of skill in the art would have been motivated to use acidic pH for making aqueous compositions with potato-derived protease inhibitors for the expected benefits in fully dissolving active ingredients and, thus, maximizing delivery of the active ingredients to the desired target under treatment or to absorbing materials.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

March 29, 2006



VERA AFREMOVA

PRIMARY EXAMINER